K081122

510(K) Summary

MAY 26 2009

Devise Proprietary Name:	Fusion Medical Cannulated Screw System
Devise Common Name:	Bone Screw
Classification Name:	HWC, Screw, Fixation, Bone
Name of Submitter:	John Riccio 1663 South Main Street Waterbury, CT 06706 Phone: (203)-823-8511 Fax: (860) 454-7562
Contact Person:	John Riccio
Date Prepared:	April 15, 2008

Summary:

This submission describes the Fusion Medical Cannulated Screw System

Indicated for:

Bone fixation of foot and ankle surgery and hand surgery, following a trauma or osteotomy. Screws and washers are for single use only.

Fusion Medical Cannulated Screw System is comprised of screws in diameters 2.0mm (length 10mm-24mm), 2.5mm (length10mm-38mm),3.0mm (10mm-38mm), 5.0mm (length 30mm-70mm), 6.5mm (length 30mm-120mm) standard bone screw. 2.0mm compression (length 20mm-24mm), 2.5mm compression (length10mm-38mm), 3.0mm compression(length 10mm-38mm), 4.0mm compression (length 22mm-56mm), 6.5mm compression (length 30mm- 120mm), 8.0mm compression (length 75mm-140mm) 9.0mm compression (length 75mm-140mm) compression screws. The Screws are made from implant quality Titanium alloy Ti6a14v. (See attachments for thread length, thread pitch and head geometry of screws.) The screws will be machine finished with a 32RMS roughness. K-wires are provided. K wires are made of 316lss. Screwdrivers, drills, and countersinks shanks are made of 17-4-ph stainless steel, condition H 900 heat treated shanks. They are quick connecting shanks that are interchangeable with the handles. Washers are provided. They are made of implant quality Ti6a14v titanium alloy. (See attachment for drawing of the washers and sizes. Depth gauges, and preparation instruments are part of the system.

Equivalence for this devise is based on similarities in intended use; material, design and operational principal to Fusion Medical Cannulated Screw System are the Osteomed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2009

Mr. John Riccio
1663 South Main Street
Waterbury, Connecticut 06706

Re: K081122
Trade/Device Name: Fusion Medical Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 22, 2009
Received: May 22, 2009

Dear Mr. Riccio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___k081122_____

Device Name: _Fusion Medical Cannulated Screws_____

Indications for Use:

For bone fixation of foot and ankle surgery and hand surgery, following a trauma or osteotomy. Screws and washers are intended for single use only

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brechtel for MPM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K081122